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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/731,554

12/09/2003

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EXAMINER

BASKAR, PADMAVATHI

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/731,554

Applicant(s)

WALKER ET AL.

Examiner

Padmavathi v. Baskar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3/29/06.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Applicant's amendment filed on 3/29/06 is acknowledged.

#### ***Status of claims***

2. Claim 21 is amended

Claims 21-23 are under investigation.

3. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

#### ***Information Disclosure Statement***

4. Information Disclosure Statement (IDS) filed on 3/29/06 is considered and a signed copy is attached to this Office action.

#### ***Specification Informalities and objection***

5. In view of updated status of priority applications, the informalities have been withdrawn.

#### ***Rejection(s) under 35 U.S.C. § 112, Second Paragraph maintained***

6. The rejection of claims 21-23 is maintained as set forth in the previous office action. The examiner maintained the rejection as the limitation "preventing" has no support in the specification (see new matter rejection). Further, applicant states that as suggested by the examiner, applicant amended the claims. The examiner disagrees with the applicant's statement because the examiner questioned the applicant's intentions but never suggested to amend the claim to recite, "preventing" as examiner is aware that the specification does not support such language. Since the claim recites identifying a subject "prior to exposure" "suspected of being exposed to" read on prevention, the examiner wanted to clarify applicant's intentions. However, applicant did not attempt to remove the limitations identifying a subject "prior to exposure" and "suspected of being exposed to" in the claim.

***Claim Rejections - 35 USC § 103 maintained***

7. The rejection of claims 21-23 under 35 U.S.C. 103(a) as being unpatentable over Ohashi et al 1998 (see IDS # C24 3/15/04, Infec.Immun, 66; 132-139) in view of Ohashi et al 1998 (see IDS # C23, 3/15/04, J.Clin. Microbiol, 2671-2680) is maintained as set forth in the previous office action.

Ohashi et al 1998 C24 teach *E.chaffeensis* and *E. canis* outermembrane proteins ranging from 23 to 30kD are major immunodominant proteins (see figure 2 A and 2B). The recombinant protein p28 of *E.chaffeensis* was used to raise antibody in Rabbits. The antibody and serum from patient infected with *E.chaffeensis* reacted with the recombinant proteins 29, 28 and 25kD proteins of *E.chaffeensis*, and a 30kD protein of *E.canis*. Further, the prior art teaches a method of inhibiting *E.chaffeensis* infection by administering immunodominant major outer membrane proteins 28 - 30kD of (see abstract and figure 9) *E.chaffeensis*. Mice immunized with recombinant p28 protein were protected from infection with *E.chaffeensis* (see page 137, left column first and second paragraphs). Thus the prior art teaches a method of inhibiting *E. chaffeensis* infection using 28-30 KD antigens of *E. chaffeensis* in a pharmaceutically acceptable carrier. However, the prior art does not teach a method of inhibiting *E. canis* infection using SEQ.ID.NO: 46. Ohashi et al. J.Clin. Microbiol, 1998 C23 teach immunodominant major outer membrane protein 30kD of *E.canis* (see abstract and figure 1). Further, the prior art teaches the serum from mice immunized with recombinant rP30 protein and the sera obtained from infected patients were reactive to rP30 antigen and 30kD protein from *E.canis* (see figure 1). The disclosed prior art protein, rP30 is 100% identical (see database Uniprot\_05, Accession number Q9ADV2\_EHRCA) with one conservative amino acid substitution, see enclosed sequence alignment) with the claimed SEQ.ID.NO: 46. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to administer readily available rP30 protein, SEQ.ID.NO: 46 from *E.canis* instead of p28 from *E.chaffeensis* in a method to inhibit *E. canis* infection with a reasonable expectation of success because Ohashi et al 1998 (C24) teach a method of inhibiting Ehrlichia infection in mice by administering p28 protein from *E.chaffeensis* and mice immunized with recombinant p28 protein were protected from infection with *E.chaffeensis*. An artisan of ordinary skills would have been motivated in applying the art disclosed by Ohashi (C24) et al to inhibit *E.canis* infection instead of *E.chaffeensis* in a subject by administering SEQ.ID.NO: 46 of *E.canis* in a pharmaceutically acceptable carrier because the prior art C24 not only teaches that mice were protected against *E.chaffeensis* infection (C24) by administering an immunodominant major outer membrane proteins 28 - 30kD of (see abstract and figure 9) *E.chaffeensis* but also clearly suggests the major outermembrane proteins 28-30kD are immunodominant and cross-reactive between *E.chaffeensis*, and *E.canis* (see page 132, left column, second paragraph) and C23 teaches 30kD of *E.canis* is an immunodominant major outer membrane protein. Therefore, the claimed invention is prima facie obvious over Ohashi et al 1998 (C24) in view of Ohashi et al 1998 (C23) absent any convincing evidence to the contrary.

Applicants arguments filed on 3/29/06 have been fully considered but they are not deemed to be persuasive.

Applicant states that Ohashi et al do not teach or suggest SEQ ID NO: 46 for inhibiting *E. canis* infection. Further applicant states Q9ADV2 EHRCA database entry was created on June 1, 2001, which is after the priority date of the present application, so this document is not prior art and submits gene bank accession number AF078555 and A17078554 (replaced by A17078553) to indicate the p30-20 referred to in AF078553 is not the same protein referred to in Q9ADV2 EHRCA, although the Q9ADV2 EHRCA sequence is given this name. Applicant states that the prior art protein provides a sequence similarity to SEQ.ID.NO: 46 but not identical to SEQ ID NO: 46. The Examiner may be considering that it is obvious from Ohashi A to try some *E. canis* protein for inhibiting infection, but it is not obvious to utilize SEQ ID NO: 46 and Applicants contend that the Examiner has engaged in an improper hindsight reconstruction, picking and choosing from multiple references that differ in their teachings.

The examiner used the prior art of record that was published before the priority date of the present application i.e., Ohashi et al 1998 Infec.Immun, 66; 132-139, Ohashi et al 1998 J.Clin. Microbiol, 2671-2680. Further, the examiner has established correct obviousness rejections because the prior art subject matter as a whole was obvious over the subject matter sought to be patented to a person having ordinary skill in the art at the time the invention was made as discussed in the above paragraph for the following reasons:

Ohashi C24 taught a method of inhibiting infection caused by Ehrlichia using the major outer membrane protein 28-30kD (immunodominant) which cross-reacts between *E.chaffeensis*, and *E.canis* (see page 132, left column, second paragraph).

Ohashi C23 taught 30KD of *E.canis* protein is an immunodominant major outer

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membrane protein. Both of the cited references are published before the filing date of priority application. Further, the prior art protein 30kD provides is similar to SEQ.ID.NO: 46. Therefore, it is correct to use under 35 U.S.C. 103 (a) rejection and hence no hindsight in constructing the rejection. Further the examiner did not use multiple references and appropriately used two references to show that the subject matter taught was obvious.

***New Claim Rejections - 35 USC § 112 based on amendment***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 21-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection because the limitation in claim 21 "preventing" is not supported by the specification.

***Remarks***

10. No claims are allowed.

***Conclusion***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP ' 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire **THREE MONTHS** from the date of this action. In the event a first response is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

12. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Padma Baskar Ph.D.



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